# FDA URGENT INFORMATION
## Recall of Clinipad Sterile Products Used in Prepackaged Procedure Kits and Trays

(You are encouraged to copy and distribute this information)

March 29, 2000

To: Hospital Administrators
Risk Managers
Director, Central Supply
Ambulatory Surgery Centers
Dialysis Centers

I am writing to let you know that certain prepackaged procedure kits and trays may include sterile antiseptic skin preparations that have been recalled by Clinipad Corporation because they may not be sterile. More than 140 manufacturers prepare a variety of procedure kits and trays that include one or more of these recalled products.

**Recommendations**

- Do not use any recalled Clinipad Corporation products.
- You should be receiving Urgent Device Recall letters from the manufacturers of affected procedure kits and trays used in your facility. Each manufacturer may handle the recall of their kits and trays differently. **Follow the directions provided by each manufacturer for their kits and trays.** Even if the kit or tray manufacturer does not contact you, you still should not use any of the recalled Clinipad products. Keep in mind that unless stated otherwise by the manufacturer, only the Clinipad product from each kit or tray is being recalled.
- If you assemble custom kits for use in your facility, be sure to remove all recalled products from these kits.

## Clinipad Corporation Products Included in the Recall

The nationwide recall of the Clinipad sterile-products line includes Povidone Iodine, Tincture of Iodine, Benzoin Tincture, Acetone Alcohol and Alcohol Antiseptic Products as well as Sterile Cliniguard® Protective Dressing labeled as "sterile." The recall includes all such products manufactured since January 1, 1997. The products (swabsticks, prep pads, towelettes, ointment tubes and pouches, and protective dressings) are distributed under the names: Cliniswab, Clinipad, Clinidine, Cliniguard, EZ Prep, Cooper Instrument Corp., Moore Medical Corp., and Rauscher. They are sold separately or packaged in various manufacturer prepared procedure kits and trays and are widely distributed to blood banks, hospitals, clinics, and retail pharmacies. They are used to prepare the skin prior to invasive procedures.

All lots of the sterile products involved in the recall have a lot number beginning with 7, 8, 9, or 0, and are labeled as "sterile" or "sterile unless opened or damaged" on the unit of use packaging.

## Reason for the Recall

The reason for the Clinipad Corporation recall is that the company has confirmed bacterial contamination in some lots of its sterile products, including one lot with *Pseudomonas aeruginosa*, *Stenotrophomonas maltophilia*, and coagulase negative *Staphylococcus*, and therefore cannot assure the sterility of its products labeled and sold as sterile. These organisms can cause skin, wound, or other infections that may be serious or life threatening in some cases.

## Additional Information

For facilities whose current procedure includes the use of the recalled prepackaged products, FDA's Center for Biologics Evaluation and Research has posted information on its web site regarding methods and products that may be used for skin preparation prior to the collection of blood and blood components. The web address is http://www.fda.gov/cber/infosheets.htm.

Additional information regarding these recalls can also be found on the FDA's MedWatch web site at http://www.fda.gov/medwatch/safety/2000/safety00.htm.

The Clinipad Corporation can be contacted at 860-571-0100.

Questions regarding this letter can be e-mailed to phann@cdrh.fda.gov; faxed to Ms. Marian Zellner at 301-594-2968; or submitted in writing to Ms. Zellner at FDA, CDRH, Office of Surveillance and Biometrics, HFZ-510, 1350 Piccard Drive, Rockville, MD 20850.

Additional copies of this notification, as well as all of FDA's medical device postmarket safety notifications, can be found on the FDA web site at http://www.fda.gov/cdrh/safety.html. Postmarket safety notifications can also be obtained through e-mail on the day they are released by subscribing to our list server. To subscribe, send a message to fdalists@archie.fda.gov. In the body of the text, type *subscribe dev-alert*.

**Reporting Adverse Events**

FDA solicits your help in collecting data on adverse events related to medical devices. Healthcare professionals employed by healthcare facilities that are subject to FDA's user facility reporting requirements should follow the reporting procedures established by their facility. Practitioners can also report incidents directly to MedWatch, the FDA's voluntary reporting program. The reports can be submitted by phone at 800-FDA-1088; by fax at 800-FDA-0178; via the MedWatch web site at http://www.fda.gov/medwatch; or by mail to MedWatch, FDA, HF-2, 5600 Fishers Lane, Rockville, MD 20857.

Sincerely yours,

David W. Feigal, Jr., MD, MPH
Director,
Center for Devices and Radiological Health